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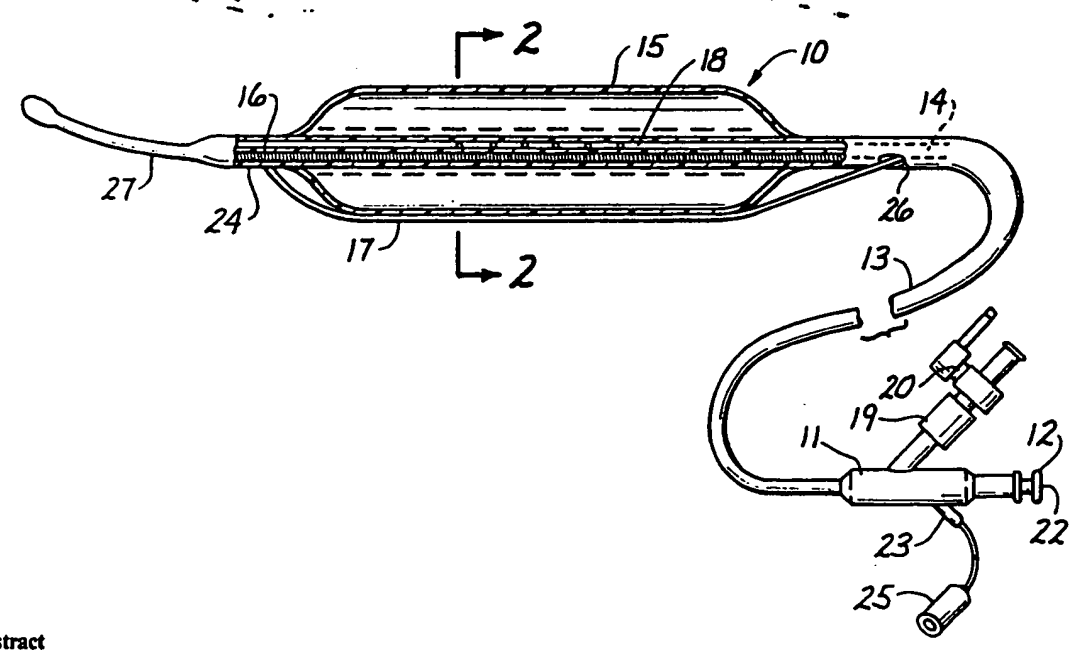

(57) Abstract

A catheter assembly (10) which permits simultaneous dilatation and incision of tissue whereby trauma and damage to the tissue due to uncontrolled tearing is reduced or eliminated comprising an elongated tubular body (13) having a distal end that carries a dilatation balloon (15) and cutting element (17) carried on the exterior of the balloon and that moves radially in concert with the exterior of the bladder as the bladder is inflated and deflated. A radiofrequency current is directed through the cutting element (17) to incise proximate tissue. Pressure can be applied to the tissue prior to cutting to facilitate separation and subsequent to cutting to inhibit bleeding.

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CATHETER WITH ELECTROSURGICAL CUTTER

Technical Field

The present invention relates generally to the field of surgical devices and more specifically to electrosurgical devices adapted to incise body tissue.

Background of the Invention

In radiofrequency electrosurgical cutting a radiofrequency current is allowed to pass from an active cutting electrode through a patient's tissue and into a grounding pad or cable. The current cuts tissue at the active cutting electrode, the cutting rate being dependant on current density through the tissue in that area. With a low current density heat is generated but no cut is achieved. With a high current density fast cutting occurs.

Current density depends upon the voltage applied to the electrosurgical circuit and the series impedance or resistance to current flow of that circuit. Current

density is also dependent upon the area the active cutting electrode presents to the patient's tissue. The smaller this area, the higher the current density. Since the area of the active electrode is fixed for a specific cutter, and the series impedance of the circuit is beyond the surgeon's control, the current density is typically adjusted by varying the voltage applied to the electrode. This adjustment is typically present on conventional electrosurgical generators.

The series impedance is dependent upon several factors which are outside the control of the surgeon. These factors may include the material and design of the active electrode, the type of tissue to be cut, and the location of the grounding pad relative to the cutting site.) Generators used in this type of surgery have a wide range of power output to accommodate a variety of procedures and devices. For example, the generator can be adjusted to either cut tissue or to merely cauterize previously cut or torn tissue.

The objective in electrosurgical cutting is to heat the cells of the tissue so rapidly that they explode into steam leaving a cavity in the cell matrix. The heat is meant to be dissipated in the steam and not to dry out adjacent cells. When the electrode is moved and fresh tissue is contacted, new cells are exploded and the incision is made. The current utilized in electrosurgical cutting is in the radiofrequency range and operates by jumping across an air gap to the tissue. This is commonly referred to as sparking.

An explanation of electrosurgical cutting theory can be found in the FORCE 1 Instruction Manual published by Valleylab of Boulder, Colorado, on March 1, 1986.

An advantage of electrosurgical cutting, particularly if it is performed utilizing a cutting electrode as disclosed in copending application Serial No. 07/522,254 filed May 11, 1990, is that overheating of adjacent tissue with accompanying desiccation and damage is limited or prevented. Thus, this procedure provides a clean cut without damage to adjacent tissue. A clean controlled cut is particularly desirable to assure that tearing does not occur in a direction away from the desired orientation of the cut.

Dilatation catheters are used to dilate body vessels, orifices and conduits such as an artery narrowed by atherosclerotic plaque or a urethra constricted by an enlarged prostate. These catheters basically consist of an elongate cannula having an inflatable non-extensible balloon or bladder at or near its distal end. A guide wire or other axial support means is often included to improve the torque control or "steerablilty" of the catheter.

The major advantage of using a dilatation catheter instead of conventional surgery is that it is less invasive. Nevertheless, the dilatation processes of the past can also result in significant trauma. As the elastomeric bladder expands, it exerts pressure on the surrounding tissue, causing the tissue to compress, deform and expand. The tissue, of course, has an inherent limit of deformability. When the dilation pressure causes the tissue to deform beyond that limit, the tissue tears apart, often to form a jagged wound. A principal object of the

present invention is to provide a dilatation catheter that permits tissue to be stressed, even beyond its limit of deformability, without experiencing uncontrolled tearing and the undesirable conditions associated therewith.

U. S. Patent 4,747,405 issued to Leckrone on May 31, 1988, U. S. Patent 4,669,469, issued June 2, 1987 to Gifford, III, et al., and PCT/US 86/02617 application of Leckrone, published June 16, 1988, are each concerned with atherecotomy devices wherein a balloon is used to position an opening in a casing about an obstruction such as plaque. The balloon does not carry a cutting element to incise tissue but does carry means for disintegrating the plaque which is generally entrapped within a hole in the casing. The balloon basically positions the hole in the casing up against and about the plaque. Thus, the balloon is not symmetrically located within the blood vessel, an outward cutting element is not present, and the blood vessel is not torn by the dilation force.

U. S. Patent 4,799,479, issued January 24, 1989 to Spears, shows use of a balloon to open up an artery and then utilizes a laser, heated wire mesh, or the like, to heat up blood trapped between the media and the plaque so that dilation will be maintained and so that a smooth wall will result.

U. S. Patent 4,273,128, issued June 16, 1981 to Lary, teaches the use of a balloon with a knife blade, or a series of knife blades, longitudinally distally removed from the balloon.

Soviet Patent 599802 published in 1976 utilizes a balloon which is located within a tube. When the balloon

is extended this forces a cutting element through a window in the tube to accomplish fenestration. Balloon pressure is not exerted against body tissue as the balloon is expanded within the tube.

German Patent 3,402,573 is concerned with a single lumen multi-purpose catheter having an extensible elastic balloon with a cutting facility for treatment of stenosis. This patent utilizes three balloons of equal size at the distal end of the catheter. Each elastomeric balloon carries small cutter elements which extend in the longitudinal direction and which are held in a trough made of hard rubber or plastic. Prior to use the cutters lie hidden in longitudinal slots of the relatively thick wall of the one-lumen catheter. Threads anchor the plate when the balloons are inflated thereby limiting the degree of penetration of adjacent plaque and possibly tissue.

U.S. Patent 4,484,579, issued to Meno, et al. on November 27, 1984, is concerned with a commissurotomy catheter which serves for separating fused heart valve leaflets. The device includes four balloons carried by a single catheter structure. In use the device fits through the valve with two balloons on each side of the valve. A nylon or similar string is attached between the pairs of balloons on each side of the valve. The balloons can be alternately expanded and contracted thereby causing the strings strung between each pair of balloons to saw or pulsate into fused portions of the heart valve leaflets and separate them. The actual cutting portion of the string is not carried on the exterior of the balloons.

The above-mentioned patents do not make use of an electrosurgical or radiofrequency cauterizing or cutting

element. Nor do the above patents either suggest or show any advantages for utilizing an inextensible bladder or balloon, i.e., a balloon which is not elastomeric (or elastic) and which can be inflated to only a selected shape and volume. Furthermore, the above discussed patents are not concerned with a radially symmetrically, generally cylindrical in shape when expanded, balloon which extends longitudinally along a body passage and a cutting element which extends longitudinally along and generally parallel to the balloon, which balloon creates a substantially uniform tangential tension in tissue being cut, and which cutting element at the same time performs the necessary cutting whereby a clean longitudinally extending incision results and uncontrolled tearing of the tissue does not occur.

The present invention is directed to overcoming one or more of the problems as set forth above.

Summary of the Invention

A catheter assembly is used to deploy a cutting element such as an electrosurgical cutter, into a body passage, such as a vessel, orifice or other body conduit. A dilatable balloon disposed at the distal end of the catheter provides means for moving the cutting element outwardly of the catheter toward the tissue to be cut. After the balloon has been dilated and the cutting element is disposed in proximity to the tissue, the element can be activated, for example with a radiofrequency signal, to cut the tissue. Then the signal can be reduced in magnitude to cauterize the cut tissue prior to deflating the balloon. Once the balloon is deflated and the cutting element

retracted into proximity to the catheter, the lower profile of the catheter will permit withdrawal from the passage.

In accordance with an embodiment of the invention a dilatation catheter assembly comprises in combination: an elongated tubular body having a distal end carrying a radially dilatable inextensible elongate member adapted to be positioned longitudinally along a body conduit and to dilate in a radially symmetrical manner and exert pressure on surrounding body tissue to provide a substantially uniform tangential tension therein; means for dilating the dilatable member to a relatively constant inextensible volume and a cutting element carried on the exterior of the dilatable member that moves radially in concert with the exterior of the dilatable member and is adapted to incise said tissue, thereby reducing damage to said tissue from dilation forces.

In accordance with another embodiment of the invention a dilatation catheter assembly comprises, an elongated tubular body having a distal end carrying a radially dilatable member adapted to be positioned in a body conduit and to exert pressure on surrounding body tissue; means for dilating the dilatable member; and an electrosurgical cutting element carried on the exterior of the dilatable member that moves radially in concert with the exterior of the dilatable member and that is adapted to incise the tissue, thereby reducing damage to the tissue from dilation forces.

In another aspect of the invention, the catheter is particularly adapted for enlarging the diameter or other cross-sectional dimension of a body passage, such as a vessel orifice or other body conduit. A conduit of

particular interest is the prostatic urethra which in the case of male patients is commonly restricted by the inward growth of the prostate gland which surrounds the urethra. Such restriction often inhibits urination resulting in the discomfort associated with frequency, urgency and control. Various attempts have been made to dilate the prostatic urethra but success has been considerably limited in terms of both efficacy and longevity.

Accordingly, another aspect of the invention is a method for dilating a body conduit, vessel or orifice comprising the steps of inserting thereinto a dilatation catheter assembly comprising an elongated tubular body having a distal end carrying a radially dilatable inextensible member adapted to be positioned in a body conduit and to dilate in a radially symmetrical manner and to exert pressure on surrounding body tissue to provide a substantially uniform tangential tension therein, and a cutting element carried on the exterior of the dilatable member; dilating the inextensible dilatable member to an extent that causes the tissue to be simultaneously stressed by the dilatable member and incised by the cutting member; radially contracting the dilatable member to cause the dilatable member and cutting element to disengage the tissue; and withdrawing the dilation catheter assembly from the conduit, vessel or orifice.

Still another aspect of the present invention is a method for dilating a body conduit, vessel or orifice. This method comprises inserting thereinto a dilation catheter assembly comprising an elongate tubular body having a distal end carrying a radially dilatable member adapted to dilate and exert pressure on surrounding body tissue and an electrosurgical cutting element carried on

the exterior of the dilatable member; simultaneously dilating the dilatable member to an extent that causes the tissue to be stressed by the dilatable member and activating the electrosurgical cutting element such that the tissue is simultaneously stressed by the dilatable member and incised by the cutting element; discontinuing activation of the electrosurgical cutting element; radially contracting the dilatable member to cause the dilatable member and cutting element to disengage the tissue; and withdrawing the dilation catheter assembly from the conduit, vessel or orifice.

Brief Description of the Drawings

The invention will be better understood with reference to the drawings wherein like numbers denote like parts and wherein:

Figure 1 is a partly cross-sectional, isometric view of one embodiment of the invention catheter;

Figure 2 is a cross-sectional view taken along line 2-2 of Figure 1;

Figure 3 is a perspective, schematic, sectional view of a portion of another embodiment of the invention illustrating the catheter positioned within a body conduit;

Figure 4 is a sectional, side view of the embodiment of Figure 3 in a deflated state;

Figure 5 is a sectional side view of the embodiment of Figure 3 in an inflated state;

Figure 6 is a cross-sectional view along line 6-6 of Figure 5;

Figure 7 is a sectional, elevational view of another embodiment of the invention;

Figure 8 is an axial cross-sectional view of a further embodiment of the invention illustrating the catheter disposed in the urethra in proximity to the prostate gland;

Figure 9 is a radial cross-sectional view taken along lines 9-9 of Figure 8;

Figure 10 is an axial cross-sectional view similar to Fig. 9 illustrating the separation of cut tissue;

Figure 11 is an axial cross-section view of a further embodiment of the invention including finger tab means for advancing the cutting element into proximity with the tissue; and

Figure 12 is an axial cross-sectional view of a further embodiment of the invention wherein the cutting element is fixed to the catheter at a location proximal to the distal end of the catheter.

Best mode For Carrying Out Invention

Figure 1 depicts a dilatation catheter assembly, generally designated 10, that may be used for dilating a body vessel or conduit, such as a ureter or urethra, to treat a blockage or other obstruction. The main elements

of catheter assembly 10 are: an adapter 11 that defines the proximal end 12 of the assembly 10 and a site for various ports to the assembly 10; a catheter body 13 having a triple lumen 14 (Figure 2); an inflatable balloon or bladder member 15; a stiffening guide wire or stylet 16 that extends longitudinally within one of the three lumens 14 of the catheter body 13; and a cutting element or electrode 17, preferably a radiofrequency cutting element 17 activatable by a radiofrequency power source 21. The electrosurgical cutting element 17 is in the nature of a wire which extends generally parallel to the longitudinally extending inflatable bladder 15.

In use, the bladder 15 is inserted into a body conduit vessel or orifice to a location where a surgical cut is required. The bladder 15 is then inflated (an inextensible bladder is generally used) with radiofrequency current being passed through the cutting element 17. This leads to the wire being moved outwardly and incising adjacent tissue in that direction.

The material used for the wire can be any of the materials currently used for electrosurgical cutting. For example, the wire can be made of stainless steel or tungsten. As illustrated in Figure 2 herein, one of the three lumens 14 serves as an inflation/deflation passageway 18, a second lumen carries the guidewire or stylet 16 and serves as a drainage/infusion passageway, and a third lumen carries the cutting element 17. In accordance with the teachings in previously mentioned copending patent application Serial No. 07/522,254, a sheath surrounding the cutting element 17 can be provided with a slit facing away from the bladder 15.

In accordance with the present invention the inflatable balloon or bladder member 15 is preferably of the inextensible or constant volume variety, that is it can, when expanded, assume only a specific size and shape. Thus, the balloon member 15 cannot extend or bulge longitudinally within the body conduit beyond its predetermined diameter or length. Since a nondistensible balloon member 15 cannot extend longitudinally, as can elastic or elastomeric balloons, it must exert the force caused by inflation of the balloon member 15 radially against an enclosing body conduit or the like. In contrast, if an elastic or elastomeric balloon is expanded within a body conduit which has one portion particularly narrowed and particularly resistant to expansion, the balloon will simply elongate rather than acting radially outwardly against the constriction.

In accordance with the present invention it is preferred to utilize a radiofrequency cutting element 17 for a number of reasons. One reason is that a radiofrequency cutting element 17 will not perform any cutting unless and until it is activated by passing a radiofrequency current through it. As a result, accidental cuts cannot be made away from the area where cutting is desired. And second, with proper control, cutting can be very sharply defined leading to a clean incision without tearing. This radiofrequency cutting or cauterizing technique can, thus, provide significant advantages over the use of prior art cutters in an apparatus of the nature disclosed herein.

In accordance with the present invention the balloon member 15 generally extends longitudinally along the body conduit and is generally symmetrically placed and

expandable therein. In this manner, as the balloon member 15 is expanded, it exerts a substantially equal tangential tension upon the tissue defining the body conduit. This results in a very clean incision which extends generally parallel to the balloon member 15. In this manner the incision can be positioned longitudinally along the body cavity rather than at an axial angle as might be the case if the tangential tension in the body conduit were not substantially uniform.

In accordance with the most preferred embodiment of the present invention, the cutting element 17 is a radiofrequency cutting element and is disposed parallel to the bladder member 15. This bladder member 15 extends longitudinally along the body conduit, is constructed of an inextensible non-elastic, non-elastomeric material and is symmetrically placed within the body cavity so that on expansion it exerts a substantially uniform tangential tension upon the tissue defining the body cavity. This configuration achieves many of the advantages associated with the present invention.

The adapter 11 serves as a site for a bladder inflation/deflation port 19 that is attached to a source of inflation medium (not shown) for inflating the bladder member 15, or to a suction source (not shown) for deflating the bladder member 15. Port 19 has a valve 20 for regulating the inflation medium or suction, as the case may be. Port 19 connects into the proximal end of an inflation/deflation passageway 18 that extends from the port 19 to the bladder member 15. The adapter 11 also serves as a site for the drainage tube inlet/outlet port 22 and a cutting element port 23. The drainage port 22 is connected to the proximal end of the lumen that carries the

guide wire or stylet 16. The drainage port 22 may serve as a site for removing fluid from the lumen or as a site for infusing fluid into the lumen.

The distal end of the catheter body has a series of drain holes 24 to facilitate flushing the lumen with fluid or voiding the bladder member 15. A "banana plug" cutting element connector 25 is affixed to the end of the cutting element port. The cutting element 17 extends from the connector 25 through the lumen of the catheter body 13, exits therefrom via an aperture 26, and continues along the exterior of the bladder member 15.

The cutting element 17 can consist of a thin wire which has an external incising edge that faces outwardly from the bladder member 15. Alternatively, the cutting element 17 may be a sharp edge, beam, or, more preferable, a radiofrequency cutting or cauterizing element 17. The element 17 and bladder member 15 are constructed such that the cutting element 17 is carried on the exterior of the bladder member 15 (at least when the bladder member is inflated) but is not capable of incising the bladder member 15.

If desired, the portion of the exterior of the bladder member 15 that is exposed to the cutting element 17 may carry a protective cover (not shown) to further guard against the bladder member 15 being incised by the cutting element 17. The cutting element 17 may be carried at a predetermined spacing from the bladder surface or directly on the surface. When carried on the surface the cutting element 17 may be an integral part of the surface or may be attached to the surface. In a preferred embodiment, the

cutting element 17 is manually extendable or retractable via the connector 25 into and out of the catheter body 13.

For use in urethral dilatation the distal end of the assembly 10 includes a coudet tip 27. Such structure may not be necessary or desirable for dilating other conduit/orifices. For urethral dilation, the assembly 10 may optionally include another lumen and "Foley" type balloon (not shown) distally of the dilatation bladder member 15 to anchor the catheter in the bladder neck of the human body and thereby facilitate correct positioning of the dilatation bladder member 15. This has the further advantage of minimizing the possibility of migration and displacement of the assembly 10. One or more of the catheter assembly components may be made of radiopaque materials to facilitate the visualization of the assembly 10 by the physician during placement of the assembly 10 in the body vessel/conduit.

The typical surgical procedure in which the catheter assembly 10 is employed, involves the following steps. Normally a cytoscope is first inserted into the vessel/conduit/orifice to be dilated. Calibration devices may be inserted through the cytoscope to facilitate measuring the extent of the vessel/conduit/orifice being dilated. The dilatation catheter of Figure 1 is then inserted to the desired depth in the vessel/conduit and positioned using fluoroscopic and/or x-ray techniques. A cytoscope lens may then be inserted through the catheter body 13 to allow visualization of the catheter and the bladder location. Fluid may be infused through the cytoscope to facilitate such visualization.

Once in position, the bladder member 15 is inflated. Such inflation causes the cutting element 17 to move radially outwardly as the bladder surface expands radially until the cutting element 17 contacts the surrounding tissue. As used herein the term "tissue" is intended to include, without limitation, normal tissue, neoplastic tissue (tumors) or an obstruction such as plaque. In accordance with a preferred embodiment of the invention the bladder member 15 is nondistensible.

Continued radial expansion of the bladder member 15 positions the cutting element 17 and causes the bladder member 15 to exert pressure on the tissue thereby subjecting the tissue to a substantially uniform tangential tension. Then a radiofrequency current can be passed through the cutting element 17.

This combined cutting and dilating action results in the tissue being expanded without being torn due to a buildup of excess stresses within the tissue. Instead, the tissue is cut in a clean, concentrated, generally longitudinal fashion by the cutting element 17 and the dilatation does not uncontrollably tear the tissue and cause excessive trauma and bleeding. The inflated bladder member 15 provides the additional benefit of acting as a tamponade to reduce bleeding.

After the vessel/conduit/orifice tissue is incised and dilated, and the blockage/obstruction is relieved, the power through the radiofrequency cutting element 17 is discontinued. Then the bladder member 15 can be deflated by operation of the inflation/deflation port valve 20. Deflation of the bladder member 15 permits a simultaneously radial retraction of the cutting element 17

out of contact with the tissue. As the bladder member 15 is deflated the cutting element 17 may be retracted via the connector 25. If desired, the cutting element 17 may be retracted prior to complete deflation of the bladder member 15 and/or the bladder member 15 reinflated and left in place to act as a tampon. Alternatively, the catheter can be withdrawn from the vessel/conduit altogether.

Figures 3-6 depict another dilatation catheter assembly of the invention, designated generally by the reference numeral 29. Only the distal end of the assembly 29 is shown. The adapter(s), as well as the various inflation/deflation ports are not shown for convenience. The distal end of the catheter is defined by a closed end catheter tube 32 which carries an inflatable, preferably inextensible, bladder member 33 on its exterior. The lumen 34 of the tube 32 is connected to the source of inflation fluid pressure/suction, as the case may be. The tube 32 has a radial aperture 35 that opens into the lumen 36 of the bladder member 33. A pair of expandable ring-shaped members 37, 38 extend around the exterior of the bladder member 33 near the distal and proximal ends thereof. One or more cutting elements 39 are affixed between the rings so that they extend longitudinally and outwardly therefrom.

Figure 3 (in solid line) and Figure 4 show both the assembly 29 in its deflated state positioned within a vessel 42 partially occluded by an obstruction 43. In order to inflate the bladder member 33, pressurized fluid is passed through catheter tube lumen 34 and aperture 35 into the bladder lumen. Inflation of the bladder member 33 in turn causes the ring members 37, 38 to expand and move the cutting element(s) 39 radially outward. Figures 3 (phantom line), 5, and 6 show the bladder member 33 in an

inflated state with the cutting element 39 incising the obstruction.

Figure 7 shows yet another dilatation catheter assembly, generally designated 46, of the invention. The assembly 46 is shown in its deflated state. This assembly 46 is similar in structure to assembly 29 except that the assembly 46 is housed within a sheath or introducer 47 and a cauterizing element 48 is connected to the cutting element 39. The sheath permits the assembly 46 to be introduced into the vessel in an unexposed manner, ejected from the end thereof for use, and retracted back into the sheath 47 after use. The ejection and retraction may be achieved by relative longitudinal movement of the sheath 47, assembly 46, or both.

A heating element 49 permits the cutting element (which in this instance must be made of a heat conducting material) to be heated to a temperature which allows the tissue to be both incised and cauterized. The heating element is connected to a heat source/control, schematically shown at 49. As an alternative the cutting element 39 can be a radiofrequency cutting element and cauterization will result along with the cutting. Also, following cutting a reduced power radiofrequency signal can be passed through cutting element 39 to accomplish further cauterization. In such an embodiment, the heat source control 49 would be replaced by a radiofrequency signal generator.

The catheter assemblies associated with the present invention are of particular advantage when used to enlarge a body passage such as a vessel, or orifice, or other body conduit. As illustrated in Fig. 8, this passage

or body conduit may include a urethra 50. In the case of a male patient, the urethra 50 is surrounded by a prostate gland 52 which has a relatively thick, inflexible outer layer of tissue. The interior tissue forming the prostate gland 52 tends to expand or grow with age, and the relatively thick outer tissue forces this growth inwardly where it tends to restrict the passage formed by the urethra 50.

In a procedure for enlarging the prostatic urethra 50, the catheter 10 (including at least a pair of lumens 14a and 14b) can be inserted into the urethra 50 with the balloon 15 positioned in a deflated state within the prostate 52. In this particular catheter illustrated in Figure 8, the electrosurgical cutting element 17 is disposed in outlying relationship with respect to the balloon 15 between the balloon 15 and the wall of the urethra 50. The cutting element 17 includes a first end 61 and a second end 63. The first end 61 is fixed to the catheter at a point 65 which in this embodiment is located at the distal end of the catheter 10. From this point 65, the cutting element 17 extends outwardly of the balloon 15, through the aperture 26 and into the lumen 14a of the catheter 10. Within the lumen 14a, the cutting element 17 is attached to one end of a spring 67 the other end of which is fixed to the catheter body 13. The cutting element 17 is energized with radiofrequency power which is transmitted through the spring 67 into the cutting element 17. From the forgoing description it is apparent that the cutting element 17 includes portions 69 which are disposed exteriorly of the catheter body 13, and portions 70 which are disposed interiorly of the catheter body 13.

In accordance with a preferred method the balloon 15 is inflated by introducing a fluid into the lumen 14b which then exits the lumen 14b through a port 54 beneath the balloon 15. As the fluid inflates the balloon 15, the cutting element 17 is carried outwardly against the force of the spring 67 into proximity with the wall of the urethra 50.

In a preferred embodiment the balloon 15 is symmetrical about a longitudinal axis which is aligned with the longitudinal axis of the catheter 10. As the balloon 15 expands, it exerts a generally equal pressure against the wall of the urethra 50 thereby placing this tissue in tension.

When the electrosurgical element 17 is activated by the radiofrequency signal, a current of high density is passed through the cells of the urethra 50 which are in close proximity to the element 17. By activating the cutting element 17 the cells are vaporized, incised, or otherwise cut along the element 17.

The tension in these cells tends to create forces which extend tangentially of the balloon 15 as shown by arrows 56 and 58 in Fig. 9. As previously adjacent cells are cut, they are separated by these tangential forces so that the circumference and hence the diameter of the urethra 50 is increased. As the balloon 15 is further inflated, new uncut tissue is brought into proximity to the cutting element 17 which continues to cut the tissue along a line, such as the dotted line 72 which extends generally radially of the catheter 10.

In Fig. 9, a progression of points along the radial cut line 72 are designated 72a, 72b, and 72c. In Fig. 10 the tangential forces illustrated by the arrows 58 and 59 are shown to have separated the two portions of cut tissue at the point 72a and these points have moved outwardly in opposite directions as shown by the points 72a'.

As the cutting progresses, it may be advantageous to further inflate the balloon 15 in order to maintain the pressure and tangential forces required for separating the cut tissue.

The radiofrequency electrical power delivered to the cutting element 17 can be provided in different forms depending on the result desired. For example, a continuous low amplitude power can be provided to facilitate cutting of the tissue while a pulsed high amplitude power can be provided to enhance cauterization of the tissue. In practice, these different forms of power may be blended to provide for different ratios of cutting and cauterizing. Ultimately the radiofrequency power is completely discontinued to halt any further cutting or cauterizing of the tissue.

Even after cutting and cauterizing have been stopped, it may be desirable to maintain or even increase the pressure in the balloon 15 in order to provide a tamponade for inhibiting bleeding in the region of the cut cells. Ultimately the balloon can be deflated to permit the cutting element 17 to move radially away from the cut tissue into proximity with the catheter body 13.

The embodiments of Figures 11 and 12 differ from the foregoing description in that the catheter 10 is not provided with a balloon 15. Rather, the means for advancing the cutting element 17 into proximity with the tissue, comprises a finger tab 84. This tab 84 engages the cutting element 17 preferably through a slot in the body 13 of the catheter. As the tab 84 is moved distally of the catheter 10, the cutting element 17 passes through the aperture 26 to increase the length of the exterior portions 69 relative to the interior portions 70. By increasing the length of the exterior portions 69, the cutting element 17 tends to move outwardly, radially into proximity with the urethra 50.

As the tab 84 moves distally of the catheter 10, the exterior portions 69 of the cutting element 17 assume progressive positions having a particular configuration. In most cases, this particular configuration will at least be arcuate. In Figure 11 wherein the aperature 26 is disposed proximally of this exterior portion 69, the particular configuration tends to be parabolic. Thus each of the progressive positions of the exterior portions 69 define a parabola. In other embodiments, this particular configuration may be ovoid.

In Figure 12, wherein the aperature 26 is disposed distally of the exterior portions 69, the particular configuration tends to take the shape of one side of a heart. Each of these configurations may have a particular advantage in the context of a particular operative procedure.

After the catheter 10 has been positioned, and the cutting element 17 has been operationally deployed into

contact with the tissue, the element 17 can be activated in the manner previously discussed. When the tissue has been cut thereby enlarging the circumferential dimension of the passage or cavity, the cutting element 17 can be withdrawn from proximity to the tissue into compliance with the catheter body 13. In the embodiments of Figures 11 and 12, this is accomplished by moving the finger tab 84 proximally thereby drawing the cutting element into the lumen 14a of the catheter 10. By moving the finger tab 84 proximally of the catheter 10, the cutting element 17 is drawn through the aperture 26 thereby decreasing the length of the exterior portions 69 relative to the interior portions 70.

In all of these preferred embodiments, both those with the balloon 15 and those with the finger tab 84, the cutting element 17 includes the interior portions 70 which are disposed in the lumen 14a and the exterior portions 69 which are disposed outside of the catheter body 13. Either the balloon 15 or the finger tab 84 provides means for increasing the length of the exterior portions 69 so that the cutting element 17 is moved radially outwardly into contact with the tissue. In both cases, the cutting element 17 moves radially into proximity with the catheter body 13 when the radial force of the balloon or the distal force on the finger tab 84 are relieved. In both cases, the spring 78 provides a proximal tension on the cutting element 17 decreasing the length of the exterior portions 69 while increasing the length of the interior portions 70.

In the embodiment of Figure 8, the aperture 26 is disposed proximally of the point 74. However, in the embodiment of Figure 12, the aperture 26 is disposed at the distal end of the catheter 10 so that the point 74 is disposed proximally of the aperture 26. In this

embodiment, the cutting element 17 is bent back on itself through the aperture 26. Nevertheless, these embodiments function similarly in that the cutting element moves radially, outwardly as its interior portion 72 are advanced distally in the catheter 10.

While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modification, and this application is intended to cover any variation, uses, or adaptions of the invention following, in general, the principles of the invention and including such departures from the present disclosure as come within known or customary practice in the art to which the invention pertains and as may be applied to the essential features hereinbefore set forth, and as fall within the scope of the invention and the limits of the appended claims.

Claims

1. A catheter assembly compris:
an elongate tubular body ha:
a dilatable member disposed on the distal end of the tubular body and adapted to be positioned in a body conduit and to dilate in a manner to exert pressure on surrounding body tissue to provide a tension in the body tissue; and
cutting means carried on the exterior of the dilatable member and having characteristics for being moved into proximity with the surrounding tissue when the dilatable member is dilated, for incising said tissue to enlarge the body conduit.

2. The assembly of Claim 1 wherein the dilatable member is an inflatable bladder that is adapted to be inflated to a predetermined volume and shape.

3. The assembly of Claim 2 wherein the cutting element is permanently affixed to the inflatable bladder.

4. The assembly of Claim 2 wherein the cutting element is removably carried on the inflatable bladder.

5. The assembly of Claim 1 wherein the cutting element is an integral component of the dilatable member.

6. The assembly of Claim 1 wherein the cutting means comprises a thin wire.

7. The assembly of Claim 1 including means for electrically energizing the cutting means to permit incision and cauterization of the tissue.

8. The assembly of Claim 1 including an open ended sheath from which the tubular body may be ejected for use and into which the tubular body may be retracted after use.

9. The catheter assembly recited in Claim 2 wherein the inflatable bladder is symmetrically disposed around the tubular body and the dilation of the inflatable bladder exerts an uniform tangential tension on the surrounding tissue.

10. The catheter assembly recited in Claim 1 wherein the cutting means comprises a radiofrequency electrosurgical cutting element.

11. A catheter adapted to cut tissue, comprising:

a tube having a longitudinal axis extending between a distal end and a proximal end of the catheter;

cutting means disposed generally at the distal end of the tube for cutting the tissue, the cutting means having portions movable radially of the axis of the catheter;

means for moving the cutting means portions radially into close proximity to the tissue to be cut;

means for activating the cutting means to cut the tissue in proximity to the cutting means; and

means for exposing previously uncut tissue to the cutting means.

12. The catheter recited in Claim 11 further comprising tamponade means for applying pressure to the cut tissue.

13. The catheter recited in Claim 11 wherein the moving means comprises a balloon having portions disposed in a fixed relationship with the tube of the catheter.

14. The catheter recited in Claim 13 wherein the balloon has a longitudinal axis generally aligned with the longitudinal axis of the tube.

15. The catheter recited in Claim 11 wherein the cutting means includes a wire and the activating means comprises means for directing an electrosurgical signal through the wire, the signal having a magnitude sufficient to cut the tissue.

16. The catheter recited in Claim 11 wherein the exposing means includes means for applying a force to the tissue to separate the cut tissue and thereby move the uncut tissue into proximity with the cutting means.

17. The catheter recited in Claim 16 wherein the exposing means includes a balloon having a curved outer surface and the force is applied to the tissue tangentially of the outer surface of the balloon.

18. The catheter recited in Claim 13 wherein the balloon has an outer surface and the cutting means includes a wire disposed in proximity to the outer surface of the balloon, the wire being movable radially with the outer surface when the balloon is inflated.

19. The catheter recited in Claim 18 wherein the balloon has first and second ends fixed to the tube, and the wire has a first end fixed relative to the first end of the balloon and a second end movable relative to the second end of the balloon.

20. The catheter recited in Claim 19 wherein the wire has a proximal end and a distal end and the first end of the wire is the distal end of the wire.

21. Tissue cutting apparatus comprising:

a supporting structure;

an electrosurgical cutter having first portions disposed in a fixed relationship with the supporting structure and second portions disposed in a movable relationship with the supporting structure;

means disposed between the supporting structure and the second portions of the cutter for moving the second portions of the cutter into proximity with the tissue to be cut; and

means for electrically activating the cutter to cut the tissue.

22. The tissue cutting apparatus recited in Claim 21 wherein the supporting structure is a catheter having a proximal end and a distal end, and the electrosurgical cutter is disposed near the distal end of the catheter.

23. The apparatus recited in Claim 22 wherein the moving means comprises an inflatable balloon having first portions fixed to the catheter and second portions movable relative to the catheter, the second portions of the balloon being disposed between the catheter and the second portions of the cutter to move the cutter into proximity with the tissue when the balloon is inflated.

24. The apparatus recited in Claim 23 wherein the first portions of the balloon include first and second ends of the balloon fixed to the catheter, and the second portions of the balloon include a central region movable relative to the catheter to move the cutter outwardly from the catheter into proximity with the tissue.

25. The apparatus recited in Claim 23 further comprising;

means for inflating the balloon to move the cutter into proximity with the tissue to be cut; and

means for deflating the balloon after the tissue has been cut.

26. The apparatus recited in Claim 23 wherein:

the cutter comprises a wire disposed to extend generally longitudinally of the catheter along the balloon;

the first portions of the cutter include a first end of the wire disposed in a fixed relationship with the catheter; and,

the second portions of the cutter include a second end of the wire disposed in a movable relationship with the catheter.

27. The apparatus recited in Claim 21 wherein the moving means is an inflatable balloon and the assembly further comprises means disposed between the cutter and the balloon for directing energy from the electrical cutter away from the balloon and toward the tissue.

28. The apparatus recited in Claim 27 wherein the electrical cutter includes a wire and the directing means includes insulation disposed along the wire between the wire and the balloon.

29. The apparatus recited in Claim 28 wherein the insulation forms a sleeve around the wire and portions of the sleeve are removed along the wire to direct the energy toward the tissue.

30. A catheter having a longitudinal axis extending between a proximal end of the catheter and a distal end of the catheter, comprising:

an elongate cutting element having a first end with a fixed relationship to the catheter and a second end with a movable relationship to the catheter; and

means for advancing the cutting element laterally of the axis of the catheter, the second end of the cutting element moving axially of the catheter in response to the operation of the advancing means.

31. The catheter recited in Claim 30 further comprising means for maintaining a tensile force on the cutting element.

32. The catheter recited in Claim 30 wherein:

portions of the catheter define a lumen and a hole extending from the lumen exteriorly of the catheter;

the cutting element has a proximal end and a distal end;

the proximal end of the cutting element is the first end of the cutting element; and

the distal end of the cutting element extends through the hole into the lumen of the catheter.

33. The catheter recited in Claim 30 wherein:

portions of the catheter define a lumen and a hole extending from the lumen exteriorly of the catheter;

the cutting element has a proximal end and a distal end;

the distal end of the cutting element is the first end of the cutting element; and

the proximal end of the cutting element extends through the hole into the lumen of the catheter.

34. The catheter recited in Claim 31 wherein the maintaining means comprises a tension spring with first portions having a fixed relationship with the catheter and second portions having a fixed relationship with the second end of the cutting element.

35. The catheter recited in Claim 34 wherein portions of the catheter define a lumen and the spring is disposed in the lumen of the catheter.

36. The catheter recited in Claim 30 wherein operation of the advancing means provides the cutting element with a plurality of different configurations each of which has the general shape of a parabola.

37. The catheter recited in Claim 30 wherein the advancing means comprises a balloon with properties for being inflated and deflated, and the catheter further comprises:

means for inflating the balloon to advance the cutting element;

means for deflating the balloon; and

means for automatically retracting the cutting element in response to deflation of the balloon.

38. A method for dilating a body conduit, comprising:

inserting into the conduit a dilation catheter assembly comprising an elongate tubular body having a distal end carrying a radially dilatable member adapted to be positioned therein and to exert pressure on surrounding body tissue to provide a substantially uniform tangential tension therein and a cutting element carried on the exterior of the dilatable member;

dilating the dilatable member to an extent that causes the tissue to be simultaneously stressed by the dilatable member and incised by the cutting element;

radially contracting the dilatable member to cause the dilatable member and cutting element to disengage the tissue; and

withdrawing the dilation catheter assembly from the conduit.

39. The method of Claim 38 including the step of cauterizing the tissue with the cutting element.

40. The method of Claim 38 wherein the cutting element is a radiofrequency cutter and the method further including the steps of:

passing a radiofrequency current through the cutter during the dilating of the dilatable member; and,

discontinuing the radiofrequency current during the radial contracting of the dilatable member.

41. The method of Claim 40 wherein the step of passing the radiofrequency current includes the steps of:

introducing a radiofrequency signal into the cutting element to cut the tissue; and

reducing the power of the radiofrequency signal to cauterize the cut tissue.

42. A method for enlarging the diameter of a passage defined by body tissue, comprising:

providing a catheter adapted to be disposed in the passage, the catheter having a cutting element and means for advancing the cutting element laterally of the catheter;

advancing the cutting element into proximity with the tissue; and

activating the cutting element to cut the tissue and enlarge the diameter of the passage.

43. The method recited in Claim 42 wherein after the activating step, the method further comprises the step of advancing the cutting element into proximity with previously uncut tissue.

44. The method recited in Claim 42 wherein after the activating step, the method further comprises the step of stretching the tissue defining the passage in order to enlarge the passage.

45. The method recited in Claim 42 wherein prior to the advancing step the method further comprises the step of deactivating the cutting element.

46. The method recited in Claim 44 further comprising the step of pressurizing the cut tissue to inhibit bleeding of the tissue.

47. The method recited in Claim 42 wherein during the activating step the tissue is cut into two portions and the method further comprises the step of separating the two cut portions of the tissue to expose uncut tissue to the cutting element.

48. The method recited in Claim 46 wherein during the providing step, the catheter is provided with an inflatable balloon and during at least one of the advancing, stretching, and pressurizing steps, the method further comprises the step of inflating the balloon.

49. The method recited in Claim 42 wherein prior to the activation step the method further comprises the step of stretching the tissue in proximity to the cutting element.

50. A method for enlarging the diameter of a passage defined by body tissue, comprising:

inserting into the passage a catheter having an inflatable balloon and a cutting element disposed in contact with the outer surface of the balloon;

inflating the balloon to move the cutting element into proximity with the body tissue;

activating the cutting element to cut the body tissue;

deflating the balloon to withdraw the cutting element from proximity with the body tissue; and

withdrawing the catheter from the passage.

51. The method recited in Claim 50 wherein prior to the activating step the method further comprises the step of stretching the body tissue.

52. The method recited in Claim 50 wherein subsequent to the activating step the method further comprises the step of pressurizing the cut tissue to inhibit bleeding.

53. The method recited in Claim 50 wherein prior to the deflating step the method further comprises the step of deactivating the cutting element to discontinue cutting the body tissue.

54. The method recited in Claim 50 wherein during the deflating step the method further comprises the step of automatically retracting the cutting element from proximity with the body tissue.

55. The method recited in Claim 50 wherein prior to the deflating step the method further comprises the step of advancing the cutting element into proximity with previously uncut tissue.

56. The method recited in Claim 55 further comprising the step of repeating the activating step.

57. A method for enlarging the diameter of a passage defined by body tissue, comprising:

inserting into the passage a catheter having a wall defining a lumen extending between a distal end of the catheter and a proximal end of the catheter, and an electrosurgical wire having first portions disposed exteriorly of the catheter and second portions disposed interiorly of the catheter, the wire including a first end fixed to the catheter and a second end movable within the lumen of the catheter to vary the length of the first portions of the wire relative to the length of the second portions of the wire;

moving the second portions of the wire distally within the lumen of the catheter to increase the length of the first portions of the wire and thereby move the first portions laterally of the catheter wall into proximity with the tissue;

activating the electrosurgical wire to cut the tissue in proximity to the wire; and

moving the second portions of the wire proximally within the lumen of the catheter to decrease the length of the first portions of the wire and thereby move the first portions laterally of the catheter wall into proximity with the catheter wall.

58. A method for enlarging the diameter of a passage defined by body tissue, comprising:

inserting into the passage a catheter having a wall defining a lumen extending between a distal end of the catheter and a proximal end of the catheter, the catheter including an electrosurgical wire with first portions disposed exteriorly of the catheter and second portions disposed interiorly of the catheter, the wire including a first end fixed to the catheter and a second end movable within the lumen of the catheter to vary the length of the first portions of the wire relative to the length of the second portions of the wire;

engaging the second portions of the wire with a finger tab extending through the catheter wall;

operating the finger tab to move the first portions of the wire laterally outwardly from the catheter wall into proximity to the tissue;

activating the electrosurgical wire to cut the tissue in proximity to the wire; and

operating the finger tab to move the first portions of the wire laterally inwardly into proximity with the catheter wall.

59. The method recited in Claim 58 wherein during at least one of the operating steps the first portions assume progressive shapes each having a particular configuration.

60. The method recited in Claim 59 wherein the particular configuration includes portions of an oval shape.

61. The method recited in Claim 59 wherein the particular configuration includes portions of a parabolic shape.

62. The method recited in Claim 59 wherein the particular configuration includes portions of a heart shape.

63. The method recited in Claim 58 wherein the wall of the catheter defines an aperture disposed between the first portions of the wire and the second portions of the wire.

64. The method recited in Claim 63 wherein the first end of the wire is disposed distally of the aperture.

65. The method recited in Claim 63 wherein the first end of the wire is disposed proximally of the aperture.

66. A catheter adapted to cut tissue, comprising:

a tube having a longitudinal axis extending between a distal end of the catheter and a proximal end of the catheter;

cutting means disposed generally at the distal end of the tube for cutting the tissue, the cutting means having portions movable radially of the axis of the tube;

finger tab means engaging the cutting means interiorly of the tube for moving the cutting means radially into close proximity to the tissue to be cut;

means for activating the cutting means to cut the tissue in proximity to the cutting means; and

the finger tab means being operable for moving the cutting means radially from the cut tissue into proximity to the tube of the catheter.

67. The catheter assembly recited in Claim 66 wherein:

portions of the tube define a slot extending axially of the catheter; and

the finger tab means extends through the slot to engage the cutting means interiorly of the tube.

68. The catheter recited in Claim 66 wherein:
portions of the tube define an aperture; and
the cutting means includes a wire extending through the aperture and having first portions disposed exteriorly of the tube and second portions disposed interiorly of the tube.

69. The catheter recited in Claim 68 wherein the aperture is disposed proximally of the first portions of the wire.

70. The catheter recited in Claim 68 wherein the aperture is disposed distally of the first portions of the wire.

71. The catheter recited in Claim 66 wherein the finger tab means is movable distally to increase the length of the first portions of the wire relative to the second portions of the wire, and is movable proximally to decrease the length of the first portions of the wire relative to the second portions of the wire.

72. The catheter recited in Claim 71 wherein the first portions of the wire assume progressive shapes in response to movement of the finger tab means, each of the progressive shapes having a particular configuration.

73. The catheter recited in Claim 72 wherein the particular configuration includes portions of an oval shape.

74. The catheter recited in Claim 72 wherein the particular configuration includes portions of a parabolic shape.

75. The catheter recited in Claim 72 wherein the particular configuration includes portions of a heart shape.

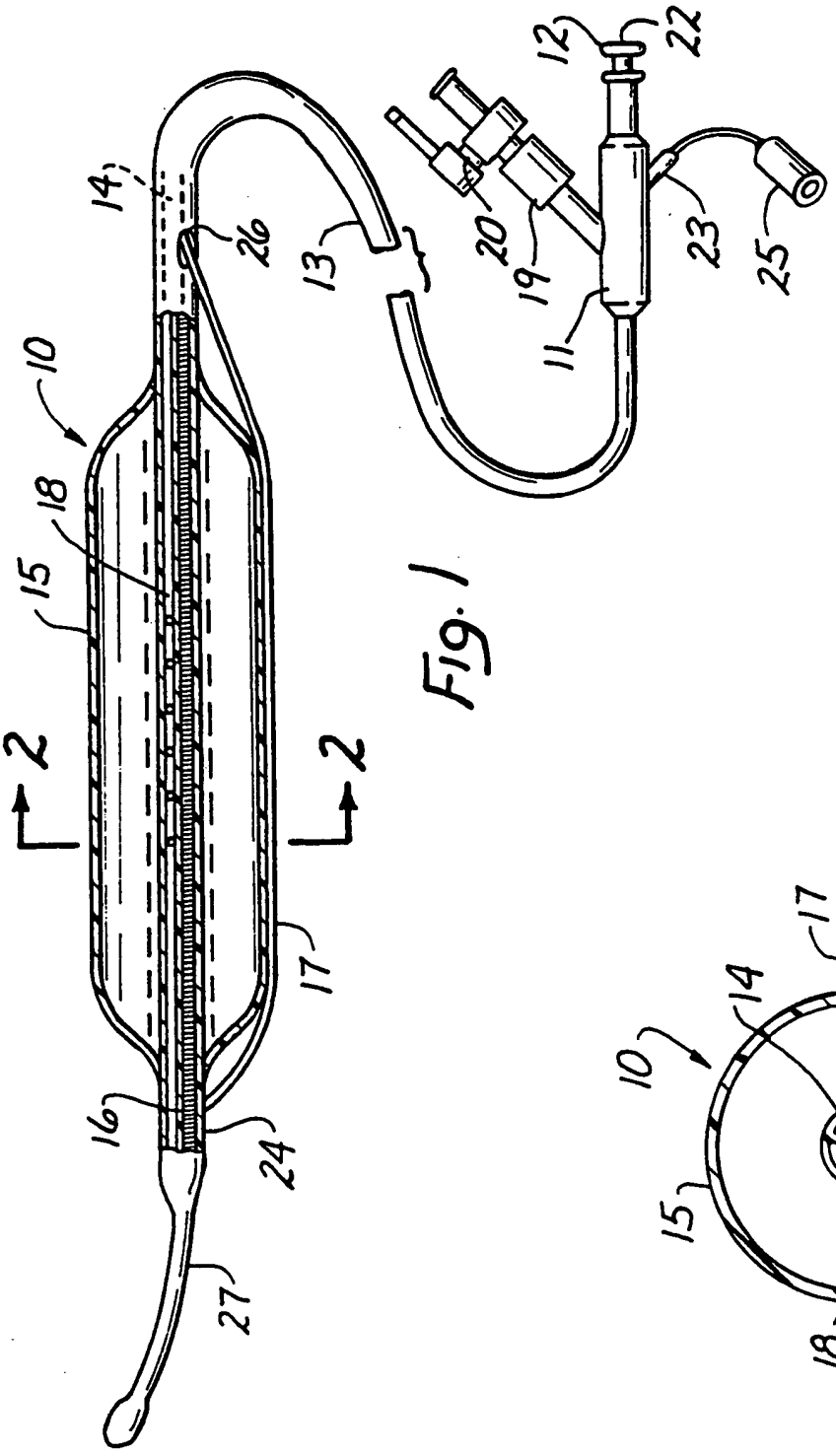


Fig. 1

Fig. 2

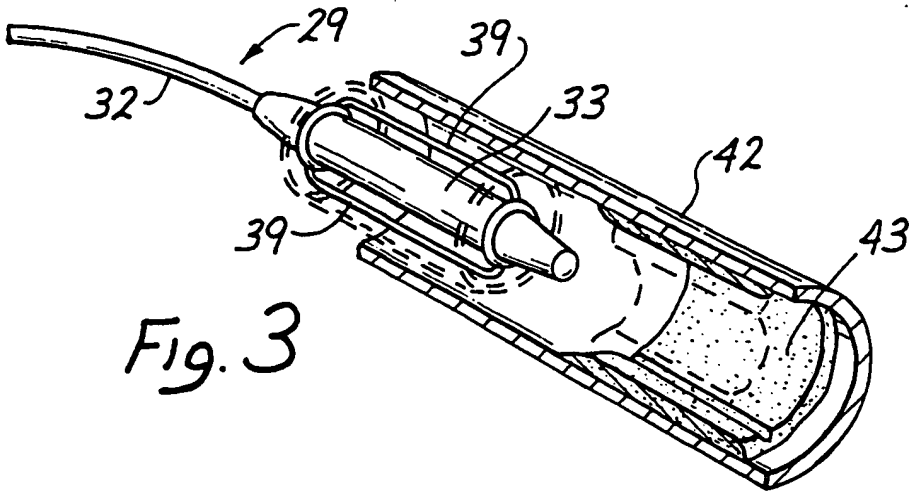


Fig. 3

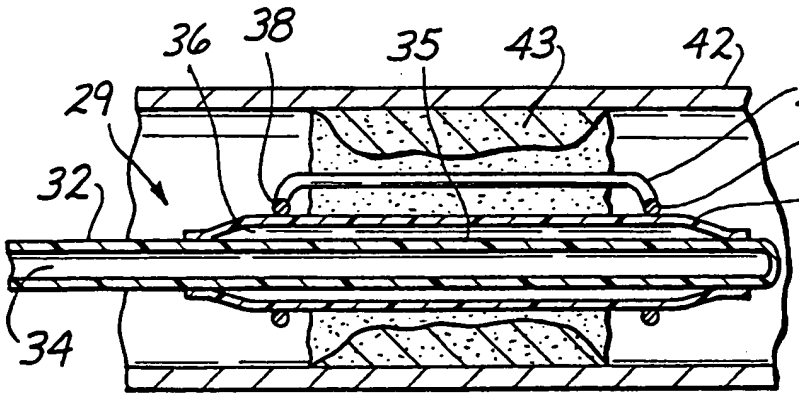


Fig. 4

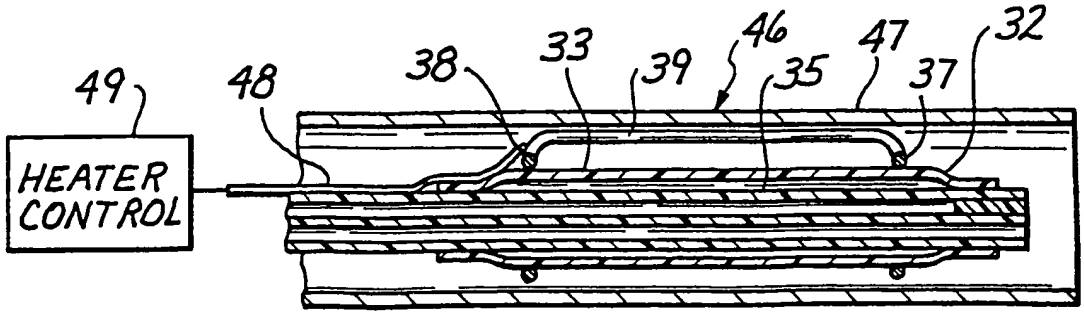


Fig. 7

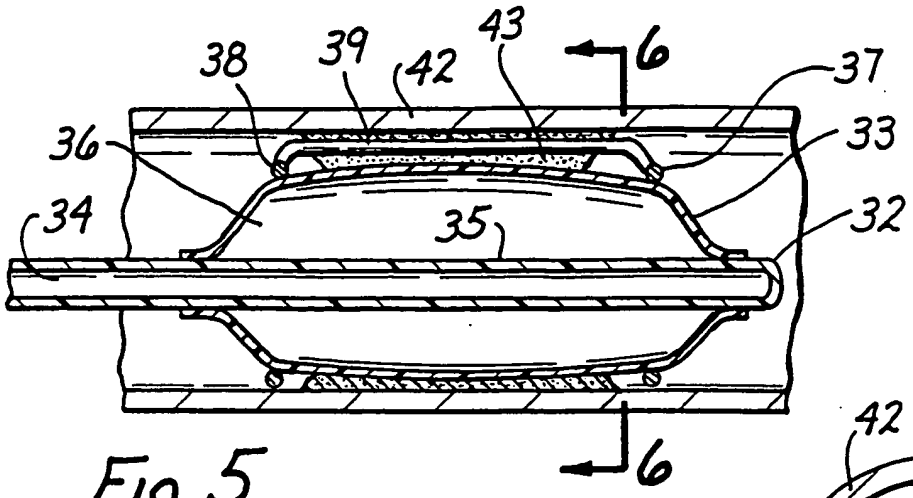


Fig. 5

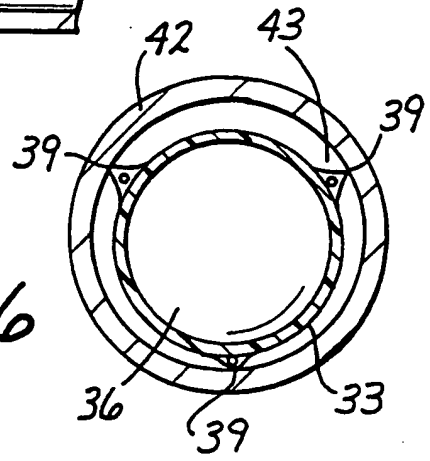
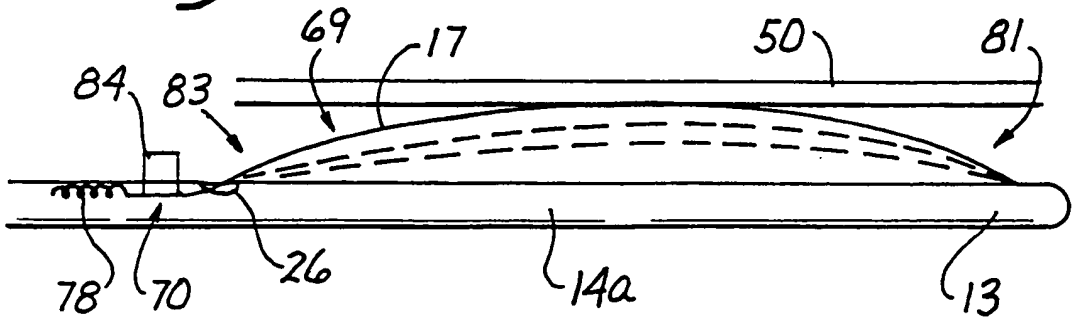


Fig. 6

Fig. 11



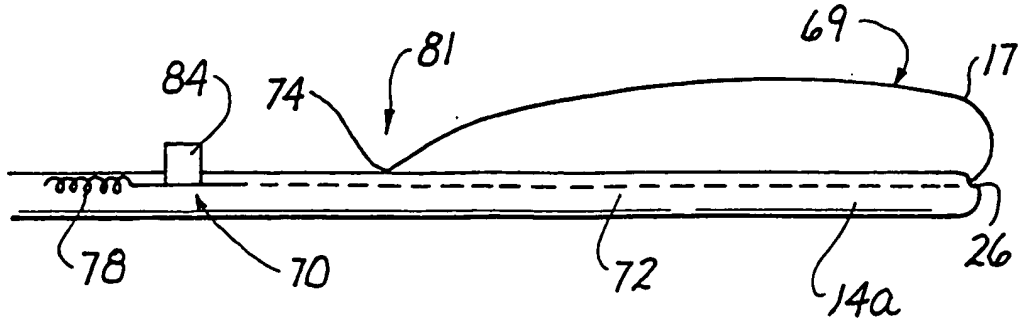


Fig. 12

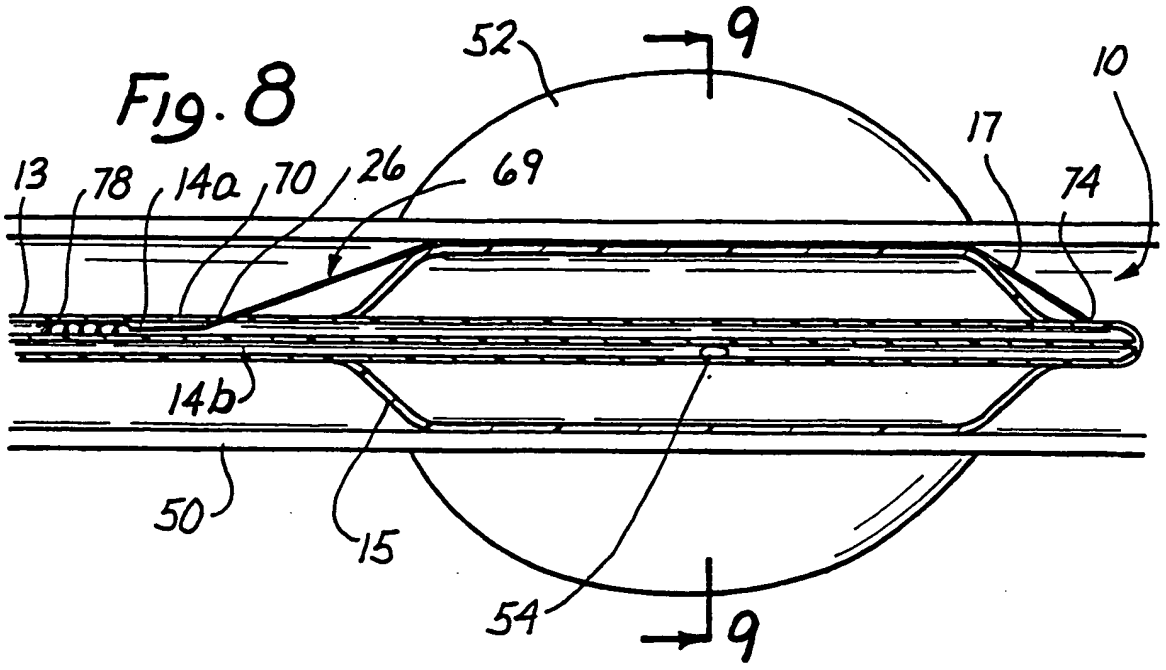


Fig. 8

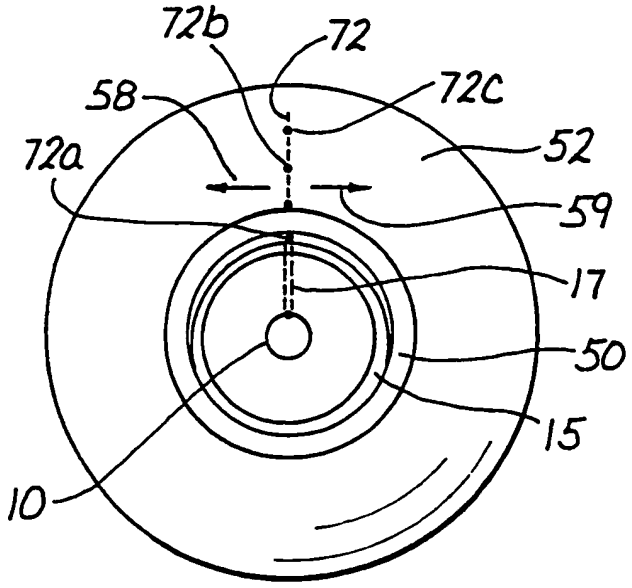


Fig. 9

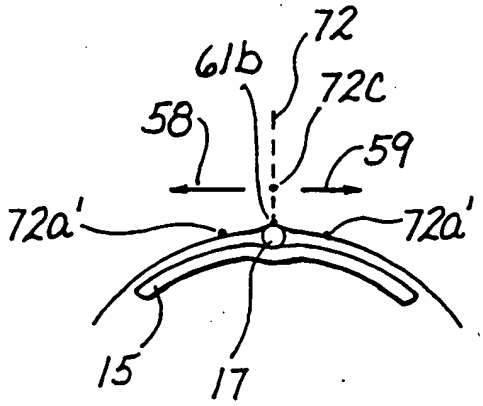


Fig. 10

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00766

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61N 1/30, A61B, 17/20 A61B 17/39
U.S.Cl.: 604/20,22, 606/39

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	606/7,28,37,39,45,49,113,159,194 604/20,22 128/751,757,898

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US, A, 4,799,479 (SPEARS) 24 January 1989 (See Figure 8).	1-7, 9-18, 38-56 8
X	US, A, 4,919,133 (CHIANG) 24 APril 1990 (See Figures 20 and 21).	1,5-7,10-11, 15-16,38-40,42 43,49
Y	US, A, 4,273,128 (LARY) 16 June 1981 (See the entire document).	8
X,P	US, A, 5,053,044 (MUELLER ET AL.) 01 October 1991 (See the entire document).	1-5,11,16,30-32,42-51,53-56
X	US, A, 4,484,579 (MENO ET AL.) 27 November 1984 (See the entire document).	1-3,6,8-9,11-14,16-20,30, 36-38,42,45, 49-56
X	US, A, 4,793,348 (PALMAZ) 27 December 1988 (See the entire document).	1-2,6,8,11-14, 16-20

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
01 June 1992	24 JUN 1992
International Searching Authority	**Signature of Authorized Officer**
ISA/US	Ronald Stright, Jr.

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

X P / Y	US, A, 5,080,660 (BUELNA) 14 January 1992 (See Figure 3).	30-33,36-37 57 / 27-29
X / Y	SU, A, 938,977 (ZAYTSEV ET AL.) 05 July 1982 (See the entire document).	1-7,10-18,21-23, 25-26,30-31, 34-35, 37-39, 42-45,50-51, 54-56 / 8, 27-29

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ..... . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.